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APPLICATION NUMBER: *60/453,680*
FILING DATE: *March 11, 2003*
RELATED PCT APPLICATION NUMBER: *PCT/US04/07409*

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EXPRESS MAIL LABEL NO. EL726087975US

03/12/03 60453680 .03112003 A/Prov

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JC960 U.S. PTO
03/11/03

Docket Number→	DKT.P.US0002P	Type a plus sign (+) inside this box →	+

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1036 U.S. PTO
60/453680
03/11/03

TITLE OF THE INVENTION (280 characters max)

A METHOD AND PROCESS THAT AUTOMATICALLY FINDS PATIENTS FOR CLINICAL DRUG OR DEVICE TRIALS

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ENCLOSED APPLICATION PARTS (*check all that apply*)

X	Specification	Number of Pages	21	___	Small Entity Status
X	Drawing(s)	Number of Sheets	3	^	Other (specify) ^

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (*check one*)

X	A check or money order is enclosed to cover the filing fee	
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^ No.

^ Yes, the name of the U.S. Government agency and the Government contract number are: ^

Respectfully submitted,

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Date: Mar. 11, 2003

___ Additional inventors are being named on separately numbered sheets attached hereto.

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6045368D.031103

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of)
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DANIEL R. DEAKTER)
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Serial No.)
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Filed)
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For A METHOD AND PROCESS)
THAT AUTOMATICALLY)
FINDS PATIENTS FOR)
CLINICAL DRUG OR DEVICE)
TRIALS

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Debbie Tingler, Sec'y to Andrew B. Morton

TRANSMITTAL SHEET

Enclosed are the following documents:

Request for Provisional Application

Provisional Patent Application

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Respectfully submitted,

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A METHOD AND PROCESS THAT AUTOMATICALLY FINDS PATIENTS FOR CLINICAL DRUG OR DEVICE TRIALS

BACKGROUND ART

This invention relates generally to the field of clinical research and more specifically to a method and system that automatically matches patients to clinical drug or device trials.

As the number of elderly people increase in the United States and their lifespans extend there is an ever increasing need for newer and safer pharmaceutical products. As such, there is a need for new drugs and medical devices to be approved more rapidly. With the mapping of the human genome it is estimated that drug targets and drugs will multiply tenfold, necessitating more clinical testing. In fact, The Pharmaceutical Research and Manufacturers of America (PhRMA) states that all drugs currently on the market are based on about 500 different targets. They expect this number to increase 600-2000%, to 3,000 to 10,000 drug targets in the coming years. However, such medical advances are outrageously expensive and have necessitated changes throughout the industry.

It is estimated to cost $880 million to bring one new drug to market. And it is estimated that the average pharmaceutical company has 70 new drugs in development. This has forced the pharmaceutical companies to consolidate for the purpose of underwriting the prohibitive expense of bringing a drug to market. The average drug takes 1 0 to 12 years to bring to market and must negotiate a series of 3 clinical trials before approval by the Food and Drug Administration (FDA) can even be granted, leaving 8 to I 0 years on a drug patent to recoup costs and turn a profit. Factoring in the governmental and managed care cost containment pressures, the pharmaceutical companies must produce one blockbuster medicine every 18 months to survive.

In summary, the pharmaceutical companies are in a position where they are producing more new drug compounds than ever before; they are about to lose the patents on many of their highly profitable, blockbuster, drugs; and they are being squeezed by the managed care industry. It is therefore critical for the pharmaceutical companies to discover, test and market the maximum number of new drugs in the minimum amount of time.

In order to speed up this process, business efficiencies are being applied to the previously haphazard clinical trials process. According to a Tufts University study, each day a study is late a pharmaceutical company can lose $ 1.3 million in lost prescription drug sales and it can be as high as $ 1 0 million for a blockbuster drug. Clinical trials are for the most part paper-based; necessarily cumbersome; and slow to monitor, process and store. One of the key factors affecting the time it takes to complete a clinical trial or study is the time it takes to recruit, screen and refer patients to the study. Only when the study is completely populated with patients can testing begin. Currently, the haphazard methods to recruit patients can take up to a year and 25% of the duration of the clinical study and thus, it becomes no surprise that 75% of all clinical studies are completed late.

There are a number of web-based clinical trial management software programs which plan, administer, and process trials for pharmaceutical companies. Although less than 15% of drug trials are e-clinical trials, this number is expected to increase to 50% or more in the next few years. Such trials will allow realtime monitoring of trials for adverse drug reactions and quality control, as well as more efficiently, move and process the prodigious amount of data generated. However, one area which still has not been adequately addressed is patient recruitment.

Traditionally, patients for studies have been enrolled from an investigator's clinic or practice, via referrals or by advertising. One prior art publication that addresses this problem using the internet, Systems and Methods for Selecting and Recruiting

Investigators and Subjects for Clinical Studies Provisional Application No. 09923,385 by Leslie Dennis Michelson and Leonard Rosenberg utilizes an online web-based system to screen and enroll investigators and patients, and matches patients to an appropriated investigator by zipcode. Another prior art is entitled Recruiting A Patient Into A Clinical Trial, Pub. No.US 2002/0099570 Al by Knight. Basically, Knight discloses how a patient with a particular disease may find a relevant study using a computer, a web browser and Internet connection. Otherwise, the need for recruiting patients is served by databases of patients available for drug trials, or by programs that flag key words on dictated summaries using a search engine for evaluation for eligibility in studies, or by web-based patient enrollment programs. There are a number of websites where patients may do a preliminary application for eligibility and thereby enroll by this means.

The known prior art does not utilize data as close to realtime as possible. It also does not systematically search all available places that patients may be found for drug trial enrollments. In particular, those websites that deal only with investigators comprise only 5% of all physicians, and a corresponding number of patients. Both Knight's and Michelson's methods do not systematically search for and find patients. It is believed that none of the known systems have a way to tap into the 95% of non-research performing physicians to find and enroll their patients into studies. And the known systems depend on patients having a computer with internet access. The method that searches dictations and flags patients is basically used in the offices of physicians with large practices who do research. These physicians are then paid for each patient found and for administering the study on that patient. However, these physicians are usually specialists who depend on referrals and it may take months for newly diagnosed patients to see the specialist and they comprise about 5% of the physician population

Therefore, based upon the foregoing, there is a need for a process that will tap a larger pool of patients more systematically, using data as close to realtime as possible with a level of precision not previously found and that will identify prospective

patients at an earlier stage of their ailment before they see the appropriate specialist, to widen their treatment options.

SUMMARY OF THE INVENTION

In light of the foregoing, it is a first object of the invention to provide a system to rapidly and precisely identify patient candidates for clinical trials comprising: a database component operative to maintain a hospital patient database and their corresponding medical records,

and a medical practice database and their corresponding plurality of specialties, and a clinical studies database

component and their corresponding plurality of clinical studies; a communications component to receive changes to said database component; a communications component to receive changes to said database component; and a processor programmed to:

periodically match compatible patients and clinical studies and generate reports to matched medical practices in said medical practice database

It is another object of the invention to to provide a computerized method for matching patients to clinical medical studies, comprising: identifying a group of medical practices; identifying at least one clinical study; identifying a group of patients from a hospital database, maintaining a database identifying each said medical practice and each patient of said group of patients from said hospital database and each said clinical study; and comparing said medical practices and said clinical studies and matching one to the other..

Other objects and advantages of the present invention will become apparent from the following descriptions, taken in connection with the accompanying drawings, wherein, by way of illustration and example, an embodiment of the present invention is disclosed.

In accordance with a preferred embodiment of the invention, there is disclosed . A method and system that automatically matches patients to clinical drug or device trials comprising:: a database component operative to maintain a hospital patient database and their corresponding medical records, and a medical practice database and their corresponding plurality of specialties, and a clinical studies database component and their corresponding plurality of clinical studies a communications component to receive changes to said database component and a processor programmed to: periodically match compatible patients and clinical studies and. generate reports to matched medical practices in said medical practice database

In accordance with a preferred embodiment of the invention, there is disclosed a computerized method for matching patients to clinical medical studies comprising: identifying a group of medical practices, identifying a group of patients in said hospital database component, identifying at least one clinical study, maintaining a database identifying each said medical practice and each said patient in said hospital database and each said clinical study, and comparing said medical practices and said group of patients in said hospital database and said clinical studies and matching one to the other..

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings constitute a part of this specification and include exemplary embodiments to the invention, which may be embodied in various forms. It is to be understood that in some instances various aspects of the invention may be shown exaggerated or enlarged to facilitate an understanding of the invention.

Figure 1 is a schematic diagram of the system according to the present invention.

Figure 2 is a flow chart of the process according to the present invention

Figure 3 is a flowchart of the process used in prioritizing search parameters

BEST MODE FOR CARRYING OUT THE INVENTION

Detailed descriptions of the preferred embodiment are provided herein. It is to be understood, however, that the present invention may be embodied in various forms. Therefore, specific details disclosed herein are not to be interpreted as limiting, but rather as a basis for the claims and as a representative basis for teaching one skilled in the art to employ the present invention in virtually any appropriately detailed system, structure or manner.

Referring now to Fig. 1 it can be seen that a system and related method for identifying patients for enrollment into a clinical trial is generally designated by the numeral 10. The system includes various organizations or entities that cooperate with one another for the purpose of identifying patients to be enrolled in medical studies. As discussed previously, Sponsors, in order to eliminate bias from clinical testing, have to outsource their research to outside entities who actually do the research. One of the first steps to perform the trial is to find and enroll patients. One of the sources for finding patients are medical practices generally designated by the numeral 20 wherein any number of specific medical practices are provided with an alphabetic suffix. The patient population generally designated by the numeral 22 and specifically each practice has a corresponding patient population each designated by an alphabetic suffix. Another set of participants are the hospitals generally designated by the numeral 24 with each individual hospital represented by alphabetic suffixes. In the preferred embodiment of this invention there is an identifier generally designated by the numeral 26 and specifically one associated with associated with each hospital and designated by the same alphabetic suffix as its corresponding hospital. The identifier consists of a communications component 28 capable of receiving and sending communications in any number of forms, including but not limited to facsimile, page, email, voice text, website data entry and instant messaging. The identifier 26 includes a computer processor 30 which includes the

necessary hardware, software and memory to implement the system and methodologies disclosed herein. The processor 30 is programmed to load the eligibility criteria, implement a best search strategy based on prioritization of search criteria also disclosed herein, and to output a report of matched patient clinical study and physician. Moreover the processor 30 is designed to access the database 36 each of which is designated by the same alphabetic suffixes as its corresponding hospital and is further comprised of a studies database 36 which contains the eligibility criteria for all the studies, a patient database 38 also designated by the same alphabetic suffix as its corresponding hospital, and contains clinical and demographic information and is a duplicate of the corresponding hospital database, and a physician database 40 also designated by the same alphabetic suffix as its corresponding hospital, and comprises a plurality of medical specialties. The processor 30 and communications component 28 are operative to maintain and update the databases. The process begins when clinical study criteria are transmitted to the communications component 28 of the identifier.

Referring now to Fig. 2 the process which is used in implementing system 10 is generally designated by the numeral 100. The process utilizes the following steps to match patients to clinical studies. At step 102 the study criteria 42 are input into the database 38 of the identifier 26. The database includes a laboratory result database 104, a radiology and pathology report database 106, dictated history and physical database 108, dictated progress notes database 110, physiological studies database 112 which included but are not limited to pulmonary function studies, cardiac catheterizations, electrocardiogram results, cardiac stress tests, esophageal manometry, hysterosalpingogram, bladder capacity test, nerve conduction tests and the like, and a genetic database 114 which consists of identified genes which are needed for studies that correct a disease caused by deficient gene. At step 118 the processor 30 finds matches between the study criteria parameters and the patients. At step 120 selected patient study matches are paired with the admitting or ordering physician, the processor can be

programmed to choose matches of 100% of criteria or a variable preset percentage. A report is generated at step 122 which consists of: patient name, title of the study that the patient quantifies for, a listing of the criteria that the patient has met and and any criteria not met, if any, and the name of the admitting or ordering physician. Step 124 utilizes the communications component 28 and transmits a report to the physician via secure means, which includes but is not limited to: Encrypted email, sealed confidential envelopes handed to physician by a specially cleared person at the hospital similar to the current mechanism that confidential HIV results are transmitted to physicians in the hospital in accordance with the Privacy Rules of The Health Insurance Portability Act. Then at step 126 the physician verifies the accuracy of the criteria, discusses treatment options with his patient, and obtains consent either to enroll the patient into a study or to refer the patient to a research site that does the study.

Referring now to Fig. 3 and to the Examples below a detailed explanation of the generation of a prioritized list of search criteria will be discussed in detail. This part of the system and method is generally designated by the numeral 200. Efficient use of processor time and resources depend on minimizing the number of free text searches. Therefore it can be seen that by matching patients based on other criteria first and free text last, the pool of patients that will be searched for free text criteria will be greatly reduced. This part of the process commences with the input of study eligibility criteria 42 to the processor 30. As the process is iterative it is a necessary first step 202 to compare the eligibility criteria to a categorized list of criteria, which in the beginning is empty. At the beginning and at all times where the prioritized list is incomplete the match will not be complete and at the next step 206 the processor extracts the first or next criteria. At step 208 the processor checks to see if the criteria is free text such as dictations of histories and physicals, discharge summaries and progress notes. This is stored on a separate list of free text criteria 210. It is then input at step 244 to an updated list of criteria, summed at step 246 to create one list of categorized criteria 248 and then fed

back at step 250 to the processor 30 at step 202 to complete one iteration of the cycle. Then the next parameter is extracted and examined to see if it is again free text 210, diagnosis 212, demographic 216, laboratory result 220, allergy 224, current medication patient is taking 228, prior treatments 232, physiological function test result 236 and lastly genotype test result at step 240. Each of the foregoing steps 208 to 240 has a corresponding list that is updated depending on which is matched. All the lists feed into updated lists at 244 and concatenated at the summing point 246 to one list and 248 feedback to the processor at 250 and at 202 the processor again compares its master list to the study eligibility criteria at 42. When the categorized list matches the study list the processor determines that the list is completed at 204 and then the list is prioritized at 252, with free text searches placed last on the list. Then this prioritized list 252 is output to the search engine 254 and at step 256 the search for eligible patients commence.

EXAMPLES

The examples below are lists of study eligibility and exclusion criteria for selected clinical drug trials. A study is listed by the title of the study in bold letters. The category of the criteria for the study is designated in bold brackets **[category]**.

EXMPLE 1:

A Phase II Safety and Efficacy Study of Clarithromycin in the Treatment of Disseminated M. avium Complex (MAC) Infections in Patients With AIDS

Eligibility

Ages Eligible for Study: 13 Years and above , Genders Eligible for Study: Both

Criteria

Inclusion Criteria

[CURRENT MEDICATION] Concurrent Medication: Allowed:

Didanosine (ddI).

Dideoxycytidine (ddC).

Zidovudine (AZT).

Acetaminophen.

Acyclovir.

Fluconazole.

Erythropoietin (EPO).

[DIAGNOSIS] Systemic Pneumocystis carinii pneumonia (PCP) prophylaxis (aerosolized or oral pentamidine,

trimethoprim / sulfamethoxazole, or dapsone).

[CURRENT MEDICATION] Maintenance ganciclovir therapy (permitted only if dose and clinical and laboratory parameters

have been stable for at least 4 weeks prior to study entry).

[CURRENT MEDICATION Maintenance treatment for other opportunistic infections if the dose and clinical and laboratory parameters have been stable for 4 weeks prior to study entry. Patients must have:

[LABORATORY RESULT] Positive results for HIV by ELISA confirmed by another method.

[LABORATORY RESULT Positive blood culture for Mycobacterium avium complex within 2 months of study entry and clinical symptoms of MAC infection.

[FROM FREETEXT] Discontinued all mycobacterial drugs (approved and investigational) for at least 4 weeks prior to the start of drug therapy (with the exception of isoniazid prophylaxis which should be discontinued at Study Day minus 14 to Study Day minus 7

[THIS WILL BE DONE AFTER THE PATIENT IS COUNCELED AND WILL NOT BE A SEARCH ENGINE CRITERON]Given written informed consent to participate in the trial.

Met the listed laboratory parameters in the pre-treatment visit.

[TREATMENT HISTORY] Prior Medication: Allowed:

Didanosine (ddI).

Deoxycytidine (ddC).

Zidovudine (AZT).

Acetaminophen.

Acyclovir.

Fluconazole.

Erythropoietin (EPO).

[DIAGNOSIS] Systemic Pneumocystis carinii pneumonia (PCP) prophylaxis (aerosolized or oral pentamidine, dapsone, trimethoprim / sulfamethoxazole).

[CURRENT MEDICIATION] Maintenance ganciclovir therapy (permitted only if dose and clinical and laboratory parameters have been stable for at least 4 weeks prior to study entry).

Exclusion Criteria

Co-existing Condition: Patients with the following conditions or symptoms are excluded:

[DIAGNOSIS] Active opportunistic infections. Maintenance treatment for other opportunistic infections will be permitted if the dose and clinical and laboratory parameters have been stable for 4 weeks prior to study entry.

[CURRENT MEDICIATION] Concurrent Medication: Excluded:

Aminoglycosides.

Ansamycin (rifabutin).

Quinolones.

Other macrolides.

Clofazimine.

Cytotoxic chemotherapy.

Rifampin.

Ethambutol.

Immunomodulators (except alpha interferon).

Investigational drugs (except ddI, ddC, and erythropoietin).

Patients with the following are excluded:

[ALLERGY] History of allergy to macrolide antimicrobials.

[CURRENT MEDICIATION] Currently on active therapy with any anti-mycobacterial drugs listed in Exclusion Prior Medications.

[CURRENT MEDICIATION] Currently on active therapy with carbamazepine or theophylline, unless the investigator agrees to carefully monitor blood levels.

Inability to comply with the protocol or judged to be near imminent death by the investigator.

[DIAGNOSIS] Active opportunistic infections.

[DIAGNOSIS] Requiring any of the excluded concomitant medications.

prior Medication: Excluded for at least 4 weeks prior to study entry:

[TREATMENT HISTORY] All anti-mycobacterial drugs (approved and investigational) with the exception of isoniazid

EXAMPLE 2:

A phase II study of lopinavir/ritonavir in combination with saquinavir mesylate or lamivudine/zidovudine to explore metabolic toxicities in antiretroviral HIV-infected subjects Eligibility

[DEMOGRAPHIC] Ages Eligible for Study: 18 Years and above , Genders Eligible for Study: Both

Criteria

Inclusion Criteria:

[TREATMENT HISTORY 1.Subject is naïve to antiretroviral treatment (subjects may not have more than 7 days of any antiretroviral treatment).

[DEMOGRAPHIC] 2.Subject is at least 18 years of age, inclusive.

[WILL BE CHECKED BY MD AND WILL NOT BE PART OF SEARCH CRITIERIA] If female, subject is either not of childbearing potential, defined as postmenopausal for at least 1 year or surgically sterile (bilateral tubal ligation, bilateral oophorectomy or hysterectomy), or is of childbearing potential and practicing one of the following methods of birth control:condoms, sponge, foams, jellies, diaphragm or intrauterine device(IUD), a vasectomized partner, total abstinence from sexual intercourse

[LABORATORY RESULT].If female, the results of a urine pregnancy test performed at screening (urine specimen obtained no earlier than 28 days prior to study drug administration) is negative.

[WILL BE CHECKED BY MD AND WILL NOT BE PART OF SEARCH CRITIERIA]Subject is not breast-feeding.

[FREE TEXT FROM PHYSICAL EXAMINATION] Vital signs, physical examination and laboratory results do not exhibit evidence of acute illness.

[DIAGNOSIS].Subject has no significant history of cardiac, renal, neurologic, psychiatric, oncologic, endocrinologic, metabolic or hepatic disease that would in the opinion of the investigator adversely affect his/her participating in this study.

[CURRENT MEDICATION] Subject does not require and agrees not to take any of the following medications for the duration of the study: midazolam, triazolam, terfenadine, astemizole, cisapride, pimozide, propafenone, flecainide, certain ergot derivatives (ergotamine, dihydroergotamine, ergonovine, and metheylergonovine), rifampin, lovastatin, simvastatin, and St. John's wort.

[TO BE PART OF CONSENT AND WILL BE REMOVED FROM SELECTION CRITERIA]Subject agrees not to take any medication during the study, including over-the-counter medicine, alcohol or recreational drugs without the knowledge and permission of the principal investigator.

[DIAGNOSIS] Subject has not been treated for an active AIDS-defining opportunistic infection within 30 days of screening.

[LABORATORY RESULT] Subject has a plasma HIV RNA level of greater than 400 copies/mL at screening.

[TO BE PART OF CONSENT AND WILL BE REMOVED FROM SELECTION CRITERIA]Subject agrees to take all doses of the study drug from the bottles provided by the sponsor (rather than other containers, i.e., „pill box").

[TO BE PART OF CONSENT AND WILL BE REMOVED FROM SELECTION CRITERIA]Subject has voluntarily signed and dated an informed consent form, approved by an Institutional Review Board (IRB)/Independent Ethics Committee (IEC), after the nature of the study has been explained and the subject has had the opportunity to ask questions. The informed consent must be signed before any study-specific procedures are performed.

Exclusion Criteria:

[ALLERGY]Subject has a history of an allergic reaction or significant sensitivity to LPV/r, INV or Combivir.

[DIAGNOSIS]Subject has a history of substance abuse or psychiatric illness that could preclude adherence with the protocol.

[LABORATORY RESULT] Screening laboratory analyses show any of the following abnormal laboratory results: ·Hemoglobin □10.0 g/dL ·Absolute neutrophil count □1000 cells/µL ·Platelet count □50,000 per mL ·ALT or AST □3.0 x Upper Limit of Normal (ULN) ·Creatinine □1.5 x Upper Limit of Normal (ULN)

[TREATMENT HISTORY] Subject has received any investigational drug within 30 days prior to study drug administration.

[TO BE DETERMINED BY RESEARCH SITE] For any reason, subject is considered by the investigator to be an unsuitable candidate for the study

EXAMPLE 3:

Iressa/Docetaxel in Non-Small-Cell Lung Cancer

Eligibility

[DEMOGRAPHIC]Genders Eligible for Study: Both

Criteria

Inclusion:

[DIAGNOSIS] Pathologically confirmed non-small cell lung cancer.

[DIAGNOSIS] Measurable, evaluable disease outside of a radiation port.

[PHYSIOLOGIC]ECOG performance status 0-2.

[LABORATORY RESULT] Adequate hematologic function as defined by an absolute neutrophil count >= 1,500/mm3, a platelet count >= 100,000/mm3, a WBC >= 3,000/ mm3, and a hemoglobin level of >= 9 g/dl.

[TREATMENT HISTORY] One prior chemotherapy regimen. This may include chemoradiation treatment.

[FROM FREE TEXT] Disease progression or recurrence within 6 months of last dose of chemotherapy in first chemotherapy regimen.

[TREATMENT HISTORY] At least a 2-week recovery from prior therapy toxicity.

[TO BE DONE WILL BE REMOVED FROM SELECTION CRITERIA] Signed informed consent.

[FROM FREE TEXT] Prior CNS involvement by tumor are eligible if previously treated and clinically stable for two weeks after completion of treatment.

Exclusion:

[TREATMENT HISTORY] Prior Iressa or other EGFR inhibiting agents

[TREATMENT HISTORY] Prior docetaxel therapy

[DIAGNOSIS] Other co-existing malignancies or malignancies diagnosed within the last 5 years with the exception of basal cell carcinoma or cervical cancer in situ.

[TREATMENT HISTORY] Any unresolved chronic toxicity greater than CTC grade 2 from previous anticancer therapy.

[FREE TEXT FROM DICTATIONS] Incomplete healing from previous oncologic or other major surgery.

[CURRENT MEDICATIONS]Concomitant use of phenytoin, carbamazepine, barbiturates, rifampicin, St John's Wort, anticoagulants.

[LABORATORY VALUE] Absolute neutrophil counts less than 1500 x 109/liter (L) or platelets less than 100,000x 109/liter (L).

[LABORATORY VALUE] . Serum bilirubin greater than 1.25 times the upper limit of reference range (ULRR).

[DIAGNOSIS] In the opinion of the investigator, any evidence of severe or uncontrolled systemic disease, (e.g., unstable or uncompensated respiratory, cardiac, hepatic, or renal disease).

[LABORATORY VALUE] A serum creatinine >= 1.5 mg/dl and calculated creatinine clearance <= 60 cc/minute.

[LABORATORY VALUE] Alanine amino transferase (ALT) or aspartate amino transferase (AST) greater than 2.5 times the ULRR if no demonstrable liver metastases or greater than 5 times the ULRR in the presence of liver metastases.

[LABORATORY VALUE] Evidence of any other significant clinical disorder or laboratory finding that makes it undesirable for the patient to participate in the trial.

[TO BE DETERMINED BY CONSENTING MD] Pregnancy or breast feeding

The patient has uncontrolled seizure disorder, active neurological disease, or Grade >= 2 neuropathy

[TREATMENT HISTORY] The patient has received any investigational agent(s) within 30 days of study entry.

[DIAGNOSIS] The patient has signs and symptoms of keratoconjunctivitis sicca or incompletely treated eye infection.

Expected Total Enrollment: 50

As can be seen from the above examples criteria vary widely from one study to the next. Currently there are about 4,000+ studies that are being conducted. In addition, finding patients for these studies is like looking for a needle in a haystack.

Based upon the foregoing the present system can find most if not all of the criteria from patient's hospital records, faster and with more accuracy and with more up to date information, than by hand searching of charts, advertising, weekly or monthly updates of a centralized database searched via its own search engine. In addition it will be able to draw upon the practices of vast number of physicians and hospitals and therefore make available to the general population treatments that might not have previously been available.

While the invention has been described in connection with a preferred embodiment, it is not intended to limit the scope of the invention to the particular form set forth, but on the contrary, it is intended to cover such alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A method and system that automatically matches patients to clinical drug or device trials comprising::

a database component operative to maintain a hospital patient database and their corresponding medical records,

and a medical practice database and their corresponding plurality of specialties, and a clinical studies database

component and their corresponding plurality of clinical studies

a communications component to receive changes to said database component and

a processor programmed to:

periodically match compatible patients and clinical studies and.

generate reports to matched medical practices in said medical practice database

2. The system according to claim 1, further comprising:

Said database component operative to maintain a patient database component identifying patients associated

with each medical practice in said medical practice database component;

Said processor programmed to:

Update said patient database component with data supplied from said hospital patient database and said medical

database component; and

Generate reports to said matched medical practices to include a listing of prospective patients.

3. The system according to claim 1, further comprising;

a searching component for searching said clinical studies database and

said searching component for searching said hospital patient database

wherein said communications component is adaptable to receive searching order instructions

4. The system according to claim 3 further comprising:

said processor programmed with a rule based system to vary search parameter priority

wherein said search parameter priority is set to search free text keyword or phrase last.

5. A computerized method for matching patients to clinical medical studies comprising:

identifying a group of medical practices;

identifying a group of patients in said hospital database component;

identifying at least one clinical study;

maintaining a database identifying each said medical practice and each said patient in said hospital database and

each said clinical study; and

comparing said medical practices and said group of patients in said hospital database and said clinical studies and

matching one to the other..

6. The method according to claim 5, further comprising:

maintaining said database to include a plurality of patient profiles associated with each said medical practice; and

notifying said medical practices of said patient profiles that match the requirements of said clinical studies.

ABSTRACT OF THE DISCLOSURE

A method and system that automatically matches patients to clinical drug or device trials with: a database component operative to maintain a hospital patient database and their corresponding medical records, and a medical practice database and their corresponding plurality of specialties, and a clinical studies database component and their corresponding plurality of clinical studies a communications component to receive changes to the database component and a processor programmed to: periodically match compatible patients and clinical studies and. generate reports to matched medical practices in the medical practice database

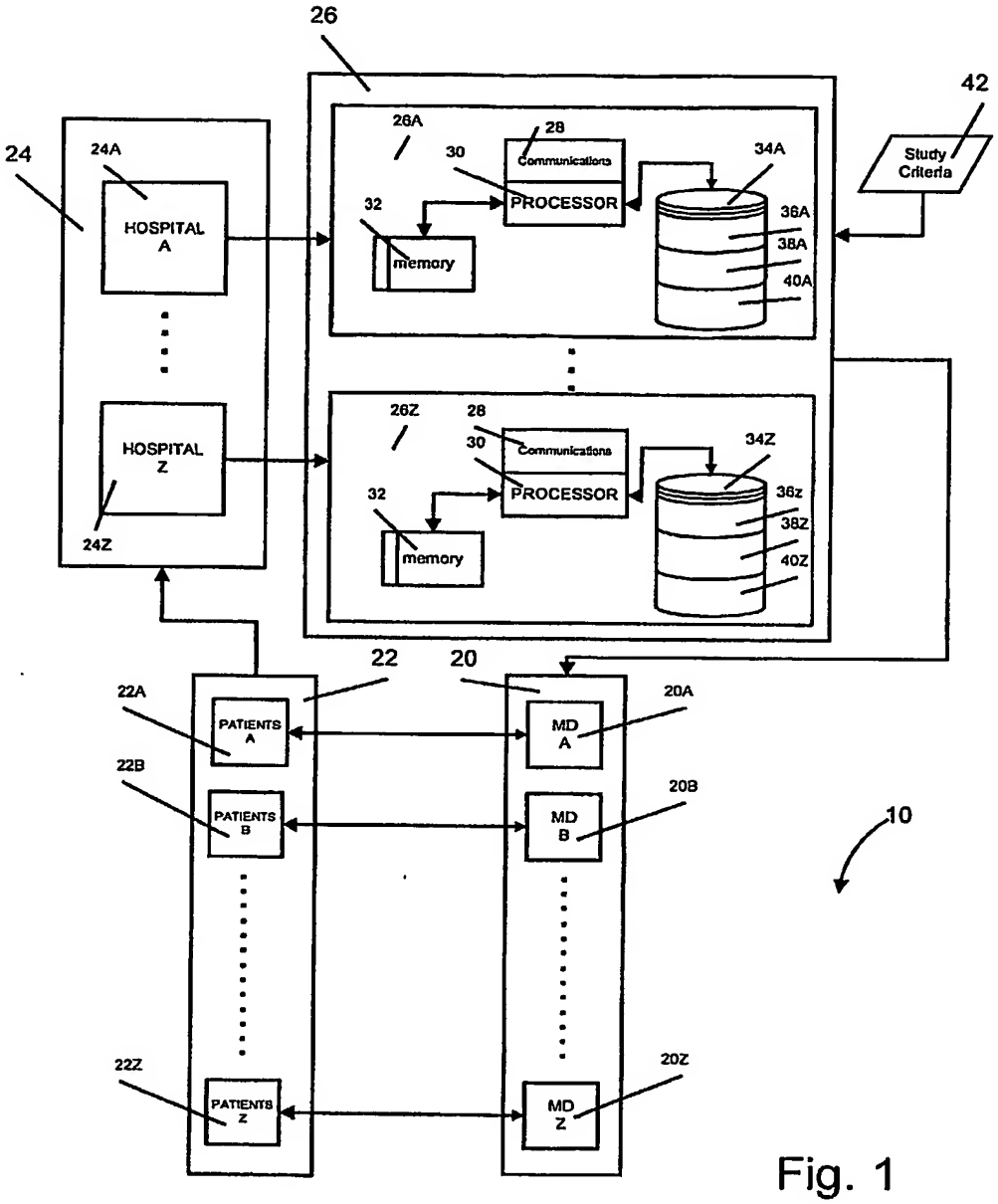


Fig. 1

Patients B

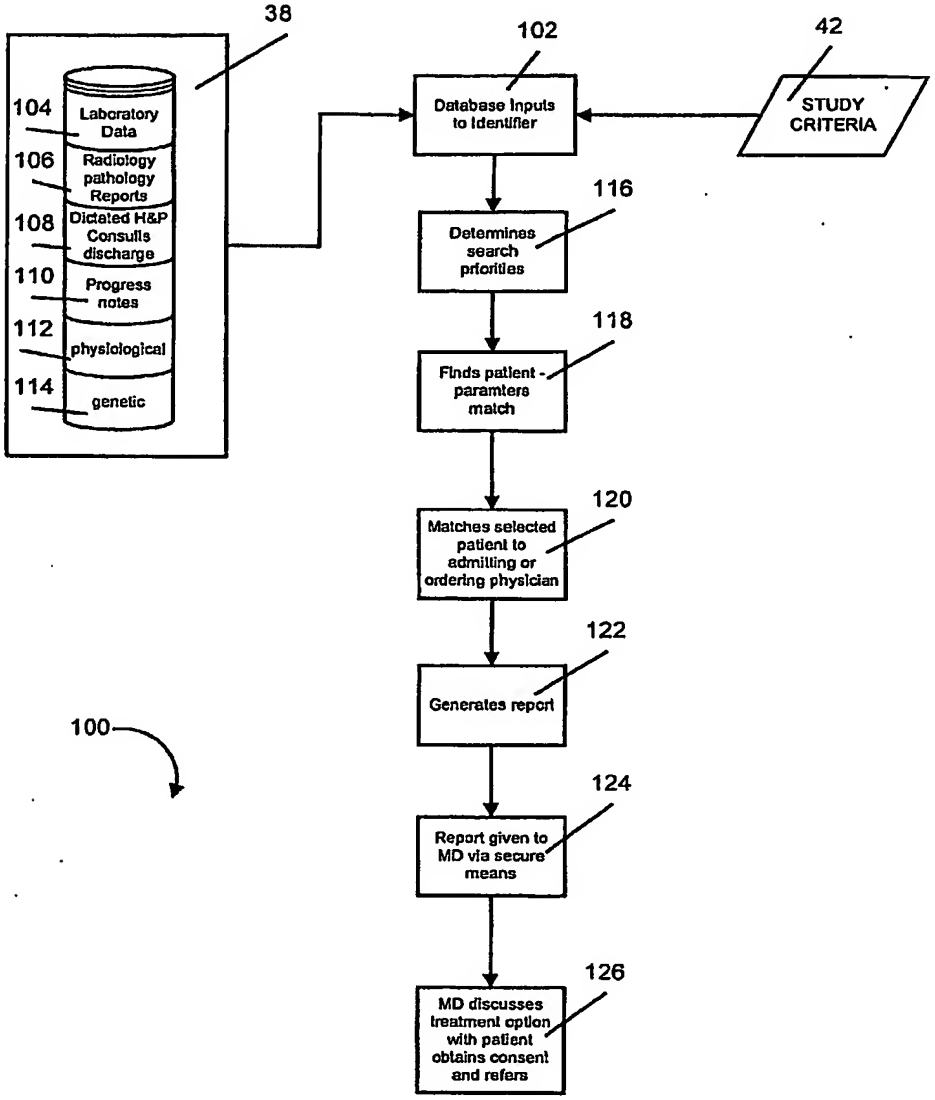
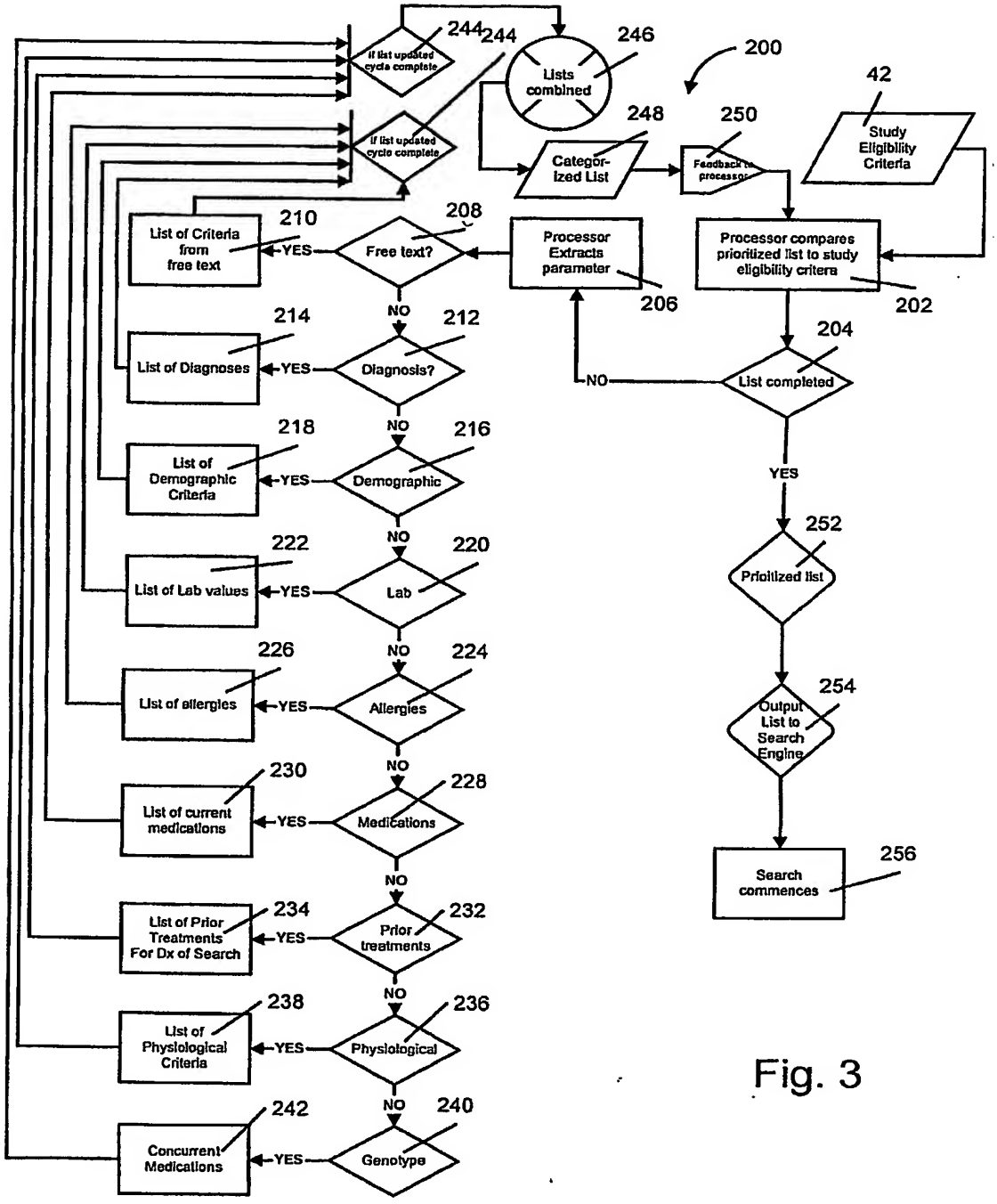

38
102
42
104
Laboratory Data
106
Radiology pathology Reports
108
Dictated H&P Consults discharge
110
Progress notes
112
physiological
114
genetic
Database Inputs to Identifier
STUDY CRITERIA
116
Determines search priorities
118
Finds patient - paramters match
120
Matches selected patient to admitting or ordering physician
122
Generates report
124
Report given to MD via secure means
126
MD discusses treatment option with patient obtains consent and refers
100

Figure 2

202


244
244
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200
42
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Lists combined
Categor-ized List
Study Eligibility Criteria
If list updated cycle complete
If list updated cycle complete
Feedback to processor
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208
List of Criteria from free text
YES
Free text?
Processor Extracts parameter
Processor compares prioritized list to study eligibility critera
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List of Diagnoses
YES
Diagnosis?
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List completed
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List of Demographic Criteria
YES
Demographic
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222
220
NO
List of Lab values
YES
Lab
Prioitized list
226
224
254
List of allergies
YES
Allergies
Output List to Search Engine
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List of current medications
YES
Medications
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234
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List of Prior Treatments For Dx of Search
YES
Prior treatments
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List of Physiological Criteria
YES
Physiological
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Concurrent Medications
YES
Genotype
Search commences

Fig. 3

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